UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,764	09/17/2001	Yehuda Assaraf	01/22501	8693

7590 12/13/2004

Anthony Castorina
G E Ehrlich
Suite 207
2001 Jefferson Davis Highway
Arlington, VA 22202

EXAMINER	
RAWLINGS, STEPHEN L	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 12/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/936,764	ASSARAF ET AL.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 March 2002 and 31 May 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-35* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed March 18, 2002 is acknowledged and has been entered.

2. Claims 1-35 are pending in the application and are currently subject to restriction.

Election/Restrictions

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Species A. Claims 1, 2, 4-14, 16-25, 27-35, insofar as the claims are drawn to a method for assessing the responsiveness of a cancer patient to antifolate-containing chemotherapy comprising searching for mutation in the human gene encoding RFC and a kit for practicing said method.

Species B. Claims 1, 3-6, 10-13, 15, 16, 18, 21-24, and 26-35, insofar as the claims are drawn to a method for assessing the responsiveness of a cancer patient to antifolate-containing chemotherapy comprising searching for mutation in the human gene encoding human DHFR and a kit for practicing said method.

Species C. Claims 1, 3-6, 10-13, 15, 16, 18, 21-24, and 26-35, insofar as the claims are drawn to a method for assessing the responsiveness of a cancer patient to antifolate-containing chemotherapy comprising searching for mutation in the human gene encoding human FPGS and a kit for practicing said method.

Species D. Claims 1, 3-6, 10-13, 15, 16, 18, 21-24, and 26-35, insofar as the claims are drawn to a method for assessing the responsiveness of a cancer patient to antifolate-

containing chemotherapy comprising searching for mutation in the human gene encoding human FPGH and a kit for practicing said method.

Species E. Claims 1, 3-6, 10-13, 15, 16, 18, 21-24, and 26-35, insofar as the claims are drawn to a method for assessing the responsiveness of a cancer patient to antifolate-containing chemotherapy comprising searching for mutation in the human gene encoding human GARTF and a kit for practicing said method.

Species F. Claims 1, 3-6, 10-13, 15, 16, 18, 21-24, and 26-35, insofar as the claims are drawn to a method for assessing the responsiveness of a cancer patient to antifolate-containing chemotherapy comprising searching for mutation in the human gene encoding human AICARTF and a kit for practicing said method.

Species G. Claims 1, 3-6, 10-13, 15, 16, 18, 21-24, and 26-35, insofar as the claims are drawn to a method for assessing the responsiveness of a cancer patient to antifolate-containing chemotherapy comprising searching for mutation in the human gene encoding human TS and a kit for practicing said method.

Species H. Claims 1, 3-6, 10-13, 15, 16, 18, 21-24, and 26-35, insofar as the claims are drawn to a method for assessing the responsiveness of a cancer patient to antifolate-containing chemotherapy comprising searching for mutation in the human gene encoding human MDR1 and a kit for practicing said method.

Species I. Claims 1, 3-6, 10-13, 15, 16, 18, 21-24, and 26-35, insofar as the claims are drawn to a method for assessing the responsiveness of a cancer patient to antifolate-containing chemotherapy comprising searching for mutation in the human gene encoding human MRP1 and a kit for practicing said method.

Species J. Claims 1, 3-6, 10-13, 15, 16, 18, 21-24, and 26-35, insofar as the claims are drawn to a method for assessing the responsiveness of a cancer patient to antifolate-

containing chemotherapy comprising searching for mutation in the human gene encoding human MRP2 and a kit for practicing said method.

Species K. Claims 1, 3-6, 10-13, 15, 16, 18, 21-24, and 26-35, insofar as the claims are drawn to a method for assessing the responsiveness of a cancer patient to antifolate-containing chemotherapy comprising searching for mutation in the human gene encoding human MRP3 and a kit for practicing said method.

4. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

5. The following claim(s) are generic: 1, 13, and 24.

6. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The technical feature that appears to link all the above species of invention is assessing responsiveness in a cancer patient to antifolate-containing chemotherapy by a process comprising searching for a mutation or mutations in a gene associated with folate metabolism or uptake in cells derived from the patient.

However, Guo et al. (*Clinical Cancer Research* **5**: 621-627, 1999) teaches a method for assessing the responsiveness of a tumor cell derived from a patient diagnosed with cancer to antifolate-containing chemotherapy, said method comprising a step of searching for deletions (i.e. mutations) in the RFC gene of the tumor cells (abstract and page 624, column 1). For example, Guo et al. teaches in Table 3 on page 624 the results of these correlative studies designed to assess the responsiveness of a patient diagnosed with cancer (and the responsiveness of the tumor cells derived from the patient) to antifolate-containing chemotherapy, wherein the expression of RFC in the tumor cells was found to be reduced as the result of an identified deletional mutation.

Therefore, the technical feature that appears to link the above species of invention does not constitute a special technical feature as defined by PCT Rule 13.2, since it does not define a contribution over the prior art.

Accordingly, the special technical features of Species A-K are as follows:

The special technical feature of Species A is searching for mutation in the human gene encoding RFC.

The special technical feature of Species B is searching for mutation in the human gene encoding DHFR.

The special technical feature of Species C is searching for mutation in the human gene encoding FPGS.

The special technical feature of Species D is searching for mutation in the human gene encoding FPGH.

The special technical feature of Species E is searching for mutation in the human gene encoding GARTF.

The special technical feature of Species F is searching for mutation in the human gene encoding AICARTF.

The special technical feature of Species G is searching for mutation in the human gene encoding TS.

The special technical feature of Species H is searching for mutation in the human gene encoding MDR1.

The special technical feature of Species I is searching for mutation in the human gene encoding MRP1.

The special technical feature of Species J is searching for mutation in the human gene encoding MRP2.

The special technical feature of Species K is searching for mutation in the human gene encoding MRP3.

Accordingly, Species A-K do not share the same or corresponding special technical feature so as to form a single general inventive concept under PCT Rules 13.1 and 13.2.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

slr
December 8, 2004